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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/159,068	09/23/1998	ELEFThERIA MARATOS-FLIER	10276/014002	4696

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/159,068

Applicant(s)

MARATOS-FLIER, ELEFThERIA

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-63 is/are pending in the application.
- 4a) Of the above claim(s) 50-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 47-49 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 50-60 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 21. Claims 47-49 and 61-63 are under examination in the instant application. Claims 47-49 are being examined only in so far as they read on the elected invention, which is a method of treatment by administration of an antagonist wherein the antagonist is a non-polypeptide drug or chemical.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 14 May 2003 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

Claims 47-49 and 61-63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in paper #22.

Applicant argues at page 3 of the response that the claims are not single means claims in that they recite a narrow stated purpose and recite "specific structural and functional limitations of the agent". Applicant's arguments are not persuasive because,

contrary to Applicant's assertions, the claims fail to recite any structural elements of any kind. The recitation of "non-polypeptide MCH antagonist" merely indicates that the agent is not a polypeptide, and therefore, can be any compound or chemical which achieves the required function. This is very "similar" to a single means claim; the previous Office action did not indicate that the claims were single means claims but that they were "similar". Therefore, the analysis of single means claims would appear to apply to the instant claims, especially in light of the fact that the instant specification fails to disclose any compounds, other than polypeptides which achieve the stated purpose and function of the claims.

With regard to the enablement of the claimed invention, Applicant asserts that in vitro and in vivo testing could be used to identify non-polypeptide MCH antagonists from a library of chemical compounds. However, as stated in the previous Office action, screening for bioactivity is basically a "wish to know" and the standard for an enabling disclosure is not one of making and testing. Applicant is claiming a method using compounds which are not disclosed or described. One of ordinary skill in the art would first need to identify compounds by screening which have the required activity and then test them to see if they will work in the claimed method. Applicant has provided no guidance in terms of structure as to which compounds may or may not be useful in the claimed method. This is not an enabling disclosure, but rather an invitation to experiment and does not meet the requirements of 112/1st paragraph.

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Claims 47-49 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record in paper #22.

Applicant asserts that the claims are not directed to drugs and or chemicals, but rather to methods, so *Fiers*, *Amgen* and *Fiddes* do not pertain to the rejection of the claims. This argument is not persuasive, because the rejection is one of lack of written description and these cases are all on point for lack of written description. The instant claims are clearly directed to methods, but the methods rely on an agent (drug or chemical) which lacks written description, therefore, the methods also lack written description because the method cannot be practiced without the agent, which is not described.

The claims provide no structure for the compounds which are encompassed in the claimed method, except that the compounds are not polypeptides. At page 7 of the response Applicant asserts that the "claims are limited structurally in that the antagonist is a non-polypeptide agent and binds to a specific protein" and that "[c]learly, binding to a specified receptor imparts a specific structure to the antagonist recited in the claims". Applicant's assertion is not persuasive because the limitation that the antagonist bind to a specified receptor is a functional limitation, not a structural limitation. Applicant is invited to provide a picture of what structure is defined by the limitation that the antagonist bind to a specified receptor. Would this encompass steroid molecules, fatty

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acid molecules, metal containing molecules, esters, heterocyclic carbon compounds, phenothiazines, morpholines, pyrimidines, tetrazoles, etc.? The types of agents encompassed by the claims are only limited by the fact that they are non-polypeptide, which encompasses every structure except compounds with peptide bonds. This clearly does not provide a structure for the compounds which are to be used in the claimed method, absent evidence to the contrary. The specification does not provide a complete structure of any drug or chemical which would have the necessary activity to function in the claimed method. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the specification fails to teach even a single drug or chemical which is a non-polypeptide compound. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud